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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,033	10/22/2001	Patrick C. Kung	044574-5040	9303
9629	7590	02/24/2004	EXAMINER	
MORGAN LEWIS & BOCKIUS LLP			LY, CHEYNE D	
1111 PENNSYLVANIA AVENUE NW			ART UNIT	
WASHINGTON, DC 20004			PAPER NUMBER	

1631

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

S.A.M.

Office Action Summary

Application No.

09/830,033

Applicant(s)

KUNG ET AL.

Examiner

Cheyne D Ly

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 83-87 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 83-87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicants' arguments filed November 24, 2003 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.
2. The cancellation of claims 1-82 has been acknowledged.
3. The species election requirement directed to cancel claims 32-34 has been withdrawal.
4. Applicant's summary of the Examiner Interview conducted on October 21, 2003 has been acknowledged.
5. Applicant's arguments directed to the previous Office Action, mailed June 24, 2003, have been acknowledged. However, the said arguments are directed to cancelled claims; therefore, said arguments are moot.
6. New claims 83-87 are examined on the merits.

CLAIM REJECTIONS - 35 U.S.C. § 112, SECOND PARAGRAPH

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 83-87 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
9. This rejection is necessitated by Applicants amendments.

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10. Specific to claim 83, steps b (ii) and c(ii), the recitation of the phrase “storing the array of expression... into a Standardized HBR array” causes the claims to be vague and indefinite because it is unclear whether “a Standardized HBR array” is a solid substrate or digital representation of the data produced from an HBR array. Clarification of the metes and bounds of the claims is required. Claims 84-87 are rejected for being dependent from claim 83.

11. Specific to claim 85 which depends from claim 83, the phrase “gene expression takes place translationally” causes the claim to be vague and indefinite because claim 83 does not recite any limitations that support “gene expression takes place translationally.” It is well known in the art that “differential gene expression” is commonly directed to the differential expression of mRNA but not the processing that occurs in translation of mRNA to protein. The limitation of “gene expression takes place translationally” is not supported by the dependent from claim 83, therefore, it is unclear how one of ordinary skill in the art to use the claimed invention as directed to “gene expression takes place translationally.” Clarification of the metes and bounds is required.

CLAIM REJECTIONS - 35 U.S.C. § 112, FIRST PARAGRAPH

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 85 and 86 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

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relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS A NEW MATTER REJECTION.

14. This rejection is necessitated by Applicants amendments.

15. The new limitations of ““gene expression takes place translationally” of claim 85 and “gene expression takes place transcriptionally” have not been found in the pointed to support for the instant new claims. Therefore, the new limitations in claims 85 and 86 are regarded as new matter as directed to the instant application as originally filed.

CLAIM REJECTIONS - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 83-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khwaja et al. (US006113907A) taken with Schena et al. (1996).

19. This rejection is necessitated by Applicants amendments.

20. Khwaja et al. discloses a method for manufacturing pharmaceutical compositions from plant extracts wherein quality control is performed via standardization and control to provide reproducible material in the predictable and consistent treatment of patients (column 2, lines 39-51), as in instant claims 84 and 87.

21. The method of Khwaja et al. comprises harvesting botanical material (whole or part), determining standardized bioactivity profile, comparing the calculated bioactivity of the botanical composition to a bioactivity fingerprint standard, and determine whether the botanical material is a pharmaceutical grade St. John's Wort (column 9, line 50 to column 2, line 7) as in instant claim 83, steps a; b and c, (i); and d.

22. The method of Khwaja et al. requires the use of molecular biology methods for generating bioactivity profiles of the plant extracts comprising a plurality of chemical components including phorbol ester (Test Array) and the bioactivity profiles are stored in arrays (column 17, lines 5-39, Table 5, and Figures 4-6), as in instant claim 83, steps b and c, (ii).

23. However, Khwaja et al. does not disclose the use of gene expression profile for generating bioactivity profiles.

24. Schena et al. discloses a method for using microarrays to examine the physiological response of cells such as heat shock response in cultured human T (Jurkat) cells under control, heat-treated, and phorbol ester treatment. Further the data generated from the said

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method are analyzed and recorded with the National Institutes of Health IMAGE software and normalized to control cells (page 10615, column 1, 1-21 and page 10617, column 2, lines 6-10). "Detectable expression was observed for all 15 of the heat shock and phorbol ester-regulated genes...Gene encoding β -actin and cytochrome c oxidase, the two most highly expressed of the 15 genes in Jurkat cells (Table 2) (page 10617, column 2, lines 11-20), as in claims 83-87.

25. Khwaja et al. discloses a method for providing reproducible material from plant for predictable and consistent treatment of patients wherein general molecular biology tools are used for quality control based on bioactivity profiles data (column 2, lines 39-51 and column 17, lines 5-39 and Table 5). While, Schena et al. discloses the use of microarrays (molecular tool) for establishing bioactivity profiles for plant extract, phorbol ester.

26. An artisan of ordinary skill in the art at the time of the instant invention would have been motivated by the improvement suggested by Khwaja et al. to use bioactivity profiles from microarrays for the quality control process of manufacturing predictable and consistent treatment for patients from plants. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to use bioactivity profiles from microarrays for the quality control process of manufacturing predictable and consistent treatment for patients from plants as taught by Khwaja et al. and Schena et al.

RESPONSE TO ARGUMENTS

27. Applicant argues that Schena et al. does not disclose a method of quality control for assessing a standardized batch and test batch wherein the herbal composition comprises multiple chemical components derived from one or more plants. Applicant's argument has

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been fully acknowledged. The prior art rejection above which has been necessitated by Applicant's amendment states that the instant invention is obvious over the prior as disclosed by the combination of Khwaja et al. and Schena et al. references.

CONCLUSION

28. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

29. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

30. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 872-9306.


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31. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

32. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

33. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (571) 272-0549 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly
2/10/04


ARDIN H. MARSCHEL
PRIMARY EXAMINER